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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PENDLETON DIVISION

FRIENDS OF ANIMALS Plaintiff,

Case No. 2:17-cv-01410-SU

v.

SCOTT PRUITT, in his official capacity as the Administrator of the U.S. Environmental Protection Agency, and

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

- 1. Plaintiff, Friends of Animals, files this action on its own behalf and on behalf of its adversely affected members against the U.S. Environmental Protection Agency (EPA) and Scott Pruitt, to challenge EPA's refusal to initiate a Special Review of the pesticide ZonaStat-H.
- 2. On or about January 30, 2012, EPA issued, pursuant to Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Registration No. 86833-1 for ZonaStat-H, the primary ingredient of which is *porcine zona pellucida*, (hereinafter, "PZP")¹.
- 3. PZP is used for population control of female wild horses (*Equus caballus*) and burros (*Equus asinus*).
- 4. Since EPA originally granted the registration, independent research has been published identifying previously undisclosed effects of PZP on wild horses. Among the findings, it is now known that PZP poses the risk of immediate physical damage to the dosed mares, can increase the mortality rate in foals born to treated mares after the PZP loses its effectiveness, can result in social disruptions among herds with treated mares by damaging long-term herd cohesion that is critical to the health of the animals, and places the wild horses at risk of a genetic bottleneck.
- 5. On May 19, 2015, Friends of Animals submitted a petition pursuant to Section 6(b) of FIFRA requesting that the EPA conduct a Special Review to consider this new, relevant scientific evidence to determine whether it would be appropriate to cancel or revise the registration of the ZonaStat-H (hereinafter, "the Petition," attached hereto as Exhibit A). Specifically, the Petition asked the EPA to reopen proceedings to determine if the new research requires reconsideration of the registration and/or the terms of use authorizing the dosing of wild mares with PZP.

¹ PZP as referred to in this complaint includes all formulations of *porcine zona pellucida* used under this registration.

- 6. On December 15, 2016, EPA responded to the petition and denied a Special Review.
- 7. Between 2012 and 2016, the Bureau of Land Management (BLM) administered approximately 2,859 doses of PZP to wild mares on public lands in the United States. BLM has asserted that it intends to increase its use of PZP as a means of controlling wild horses in western states, including in Oregon.
- 8. For example, on or about June 21, 2017, BLM announced its intention to implement a 10-year plan to manage wild horses located on the Stinkingwater Horse Management Area (HMA), located on federal public lands in Harney County, Oregon, approximately 25 air miles east of Burns, Oregon. Under this plan, BLM would regularly roundup and remove wild horses from the HMA to regulate their population. While many of the horses would be permanently removed from the HMA, some would be returned. Mares that are returned to the HMA would first be dosed with PZP.
- 9. Even more recently, BLM announced a similar plan to use PZP on mares residing on the Hog Creek HMA, located on federal public lands in Malheur County, Oregon, approximately eight miles west of Harper, Oregon.
- 10. Overall, it is clear that BLM continues to administer PZP to wild horses in Oregon and other Western states despite the most recent scientific evidence demonstrating that the drug can potentially harm the environment, including the dosed mares.
- 11. Friends of Animals now comes to this Court seeking judicial review of EPA's determination to deny the Petition. That determination was made contrary to the legal standards governing the granting and denial of pesticide registrations in FIFRA, and against the weight of the most recent and relevant scientific evidence regarding PZP's impacts on the environment. Friends of Animals also seeks an award of costs and attorney fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412.

JURISDICTION AND VENUE

- 12. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 (federal question) and 7 U.S.C. § 136n(a) (authorizing judicial review by federal district courts in cases where the Administrator refuses to cancel or suspend registration or to change a classification not following a hearing).
- 13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e), as the violations complained of herein occurred in the district of Oregon and this case is properly filed in the Pendleton Division per Civil Local Rule 3.2 because a substantial part of the events or omissions giving rise to the claim occurred and will continue to occur Harney and Malheur counties.

PARTIES

organization, incorporated in the state of New York since 1957. Friends of Animals works to cultivate a respectful view of nonhuman animals, free-living and domestic. Friends of Animals' goal is to free animals from cruelty and institutionalized exploitation around the world. Friends of Animals informs its members about animal advocacy issues and its progress in addressing them through its magazine, *ActionLine*, its website, and other public reports. Friends of Animals is a leading organization advocating for the preservation of wild horses on public lands. Friends of Animals has published articles on wild horses in Oregon and across the West. Members of Friends of Animals regularly visit public lands to view, appreciate, study, and photograph the wild horses there. Friends of Animals has also worked extensively to educate the public about wild horses and the negative impacts of PZP. For example, Friends of Animals members have visited and studied wild horses and

their habitats within Harney and Malheur counties on multiple occasions in the past year, and have plans to do so again in the early spring of 2018.

- 15. Defendant Scott Pruitt, in his official capacity as administrator of the EPA, has authority to authorize a special review to consider scientific evidence demonstrating the need to cancel the registration of the contraceptive ZonaStat-H, the primary ingredient of which is *PZP*.
- 16. Defendant EPA is the federal agency responsible for federal regulation of pesticides manufactured or distributed in the United States.

LEGAL BACKGROUND

A. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

- 17. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered (licensed) by EPA.
- 18. Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment."
- 19. FIFRA allows the Administrator of the EPA to issue a notice of cancellation of a pesticide when the pesticide used in accordance with widespread and commonly recognized practice, causes unreasonable adverse effects on the environment.
- 20. The Administrator may consider whether to issue a Notice of Special Review on his own initiative or at the suggestion of any interested party. 40 C.F.R. § 154.10.
- 21. The Administrator may conduct a Special Review of a pesticide use if it is determined that the pesticide may result in harm to nontarget organisms that are exposed to the pesticide. 40 C.F.R. § 154.7(a)(3).

- 22. The Administrator may issue a Notice of Special Review if the agency determines that one or more uses of a pesticide may "otherwise pose a risk to humans or the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration." 40 C.F.R. § 154.7(a)(6).
- 23. FIFRA includes a judicial review provision which authorizes a district court to review "the refusal of [EPA] to cancel or suspend a registration ... and other final actions of [EPA] " 7 U.S.C. §136n(a).

B. Administrative Procedure Act (APA).

- 24. The Administrative Procedure Act (APA) provides that "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).
- 25. Under the APA, the term "rule" means "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy " 5 U.S.C. § 551(4).
- 26. Under the APA, a person "adversely affected or aggrieved" by certain agency actions is entitled to judicial review. 5 U.S.C. § 702. Reviewable agency actions are limited to those "made reviewable by statute" and other "final agency action[s]." 5 U.S.C. § 704. A reviewing court may set aside final agency action found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

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FACTUAL BACKGROUND

A. The History of Wild Horses in America.

- 27. Wild horses, members of the Equus genus, evolved in North America approximately five million years ago.
- 28. The North American populations likely went extinct 10 to 12 thousand years ago.
- 29. In the mid-1500s, Spanish conquistadors returned domestic horses to the continent, and since then, some domestic horses escaped captivity onto western rangelands where they continue to roam as wild horses.
- 30. These wild horses developed distinct behaviors from their domestic counterparts, and serve as plausible proxies for the extinct American species.
 - 31. By 1900, there were two to five million wild horses in the United States.
- 32. However, the population started to decrease in the early 1900s because hunters and ranchers started killing wild horses and driving them off the land out of concern that wild horses were destroying land and resources wanted by ranching and hunting interests.
- 33. While it was not clear that there were too many horses, or that the land was incurring damage due to the presence of the horses, by the 1930s the United States Forest Service and the United States Grazing Service (the predecessor to the BLM) responded to political pressure by removing hundreds of thousands of wild horses from federal property.
- 34. From 1934 to 1963, the Grazing Service (and from 1946 onward, BLM) paid private contractors to kill wild horses and permitted their carcasses to be used for pet food. Additionally, ranchers were often permitted to round up any horses they wanted, and the

Forest Service would shoot the remaining animals. These policies drastically reduced the amount of wild horses in the United States.

- 35. By the 1960s, many Americans grew concerned that wild horses in the western United States might once again become extinct due to these human-related activities.
- 36. In 1971, a bipartisan Congress passed the Wild Free-Roaming Horses and Burros Act (WHBA), 16 U.S.C. §§ 1331 et seq., and found that, "wild free-roaming horses and burros are living symbols of the historic and pioneer spirit of the West; that they contribute to the diversity of life forms within the Nation and enrich the lives of the American people; and that these horses and burros are fast disappearing from the American scene."
- 37. Upon finding this, Congress stated its policy was that "wild free-roaming horses and burros shall be protected from capture, branding, harassment, or death, and to accomplish this they are to be considered in the area where presently found as an integral part of the natural system of public lands." 16 U.S.C. § 1331.
- 38. The WHBA requires BLM to "protect and manage wild free-roaming horses and burros as components of the public lands . . . in a manner that is designed to achieve and maintain a thriving, natural ecological balance on the public lands." 16 U.S.C. § 1333(a).
- 39. Section 3 of the WHBA grants BLM the limited authority to maintain a thriving natural ecological balance (TNEB) on public lands by permanently removing "excess" horses from public lands, but only after BLM specifically determines that: (1) "an overpopulation [of wild horses] exists on a given area of the public lands," and (2) "action is necessary to remove excess animals." 16 U.S.C. § 1333(b)(2).
- 40. Despite the protections provided by the WHBA, in 2017, there are only roughly 59,000 wild horses on BLM administered public lands in the United States. Most of

these horses are managed in small herds, many of which are less than 200 horses, spread out over vast federal public lands in the western United States.

B. Wild Horse Contraception and PZP.

- 41. Reduction of free-roaming horse and burro populations through use of contraception has been a goal of some researchers and organizations since the early 1970s. Various methods have been attempted leading up to the use of PZP.
- 42. PZP is extracted from pig ovaries and is a composite of four different acidic glycoproteins, ZPl, ZP2, ZP3, and ZP4. The antibodies bind to the ZP glycoproteins that surround the egg of the injected animal, alter the glycoproteins' conformation, and block the attachment of sperm, thus preventing fertilization.
- 43. On September 16, 2009, the Humane Society of the United States submitted an application to the EPA for a first registration of ZonaStat-H. The active ingredient in ZonaStat-H is PZP.
- 44. The requested application use was for the control of wild and feral horse and burro populations on private and public lands.
- 45. The application proposed that ZonaStat-H be administered to target animals via intramuscular injection in the hip or gluteus muscles either by hand delivery (injection), jab-stick delivery, or remote (dart) delivery.
- 46. EPA published a Notice of Receipt for this first registration on January 27, 2010. It was disclosed in this notice that the Humane Society requested waivers for most of the studies ordinarily required from an applicant seeking a pesticide registration, including a toxicity study, ecological effects and environmental fate guideline study, and an efficacy study.
 - 47. The requested waivers were granted by the EPA.

- 48. The Humane Society sought the registration on studies conducted in the 1990s regarding the efficacy of the drug as a wild horse and burro contraceptive.
- 49. These studies conclude that PZP can be highly effective at reducing fertility rates among wild mares.
- 50. These studies did not probe into possible adverse impacts on wild horses, their foals, or the environment.
- Most of these reviews were published by Dr. Jay Kirkpatrick, a veterinarian 51. who helped pioneer the use of PZP as an animal contraceptive and whose lab manufactured ZonaStat-H for use on wild horses.
- 52. Based upon the information provided by the Humane Society, EPA granted the registration on or about January 30, 2012.
 - 53. On July 6, 2017, EPA approved an amended label for Zonastat-H.
- 54. According to EPA approved label, PZP is only approved for use on female wild horses and burros that are capable of doing environmental damage.
- 55. Since its approval as a registered pesticide, PZP has been in widespread use to control wild horse populations. For example, BLM, which has jurisdiction over the largest number of wild horse herds on federal public lands, has administered approximately 2,859 doses of PZP to wild mares since 2012, including mares in Oregon.
- 56. BLM currently has plans to administer PZP to additional horses in the Stinkingwater HMA, approximately thirty miles east of Burns, Oregon and in the Hogs Creek HMA in Malheur County, Oregon.

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C. Friends of Animals' Petition.

- 57. Recent research has demonstrated that PZP impacts mare stress and reproductive physiology, and application of PZP to mares can also change behavior.
- 58. New information has revealed that PZP is causing undue physical, social and biological harm to America's wild horses, both individually and collectively; and its continued use may result in genetic bottleneck that can threaten the continued existence of these animals in the wild.
- 59. For instance, mares which change groups more often (such as those treated with PZP) can exhibit increased stress levels and this increased stress is maintained for at least two weeks after the group changes occur.
- 60. PZP can also increase the mortality rate in foals born to treated mares after the PZP loses its effectiveness. After the administered PZP is no longer effective to prevent conception, the drug's residual effect contributes to increased reproductive behaviors at suboptimal times; increases the likelihood that birth will also occur at suboptimal times; and quantifiably increases the likelihood of foal mortality.
- 61. Mares that receive PZP over extended periods are more likely to cycle, become pregnant, and subsequently give birth in the fall and winter months. This is significant because offspring born at this time face nutritional and thermoregulatory challenges not experienced by their counterparts born during the normal foaling season (during the spring and summer), potentially making developmental benchmarks difficult to achieve.
- 62. After contraception management, PZP recipients both attract and initiate more instances of reproductive behavior and are more often the harem male's nearest neighbor during the fall and winter, indicating that group spreads are reduced. These changes can be important as horses typically spread out in the fall and winter months to find scarce forage. Such changes represent an increase in energy expenditure and a

potential decrease in nutrient intake during a time of year when sufficient energy reserves are at a premium.

- 63. Mares treated for more consecutive years are more likely to exhibit the behavioral and physiological changes outlined above, decreases in ovarian function, and perhaps, permanent infertility.
- 64. Where, as is often the case, the plan is to vaccinate non-reproductive females (those between one and three years old), it will preclude young mares from forming the important social attachments between males and females typically made when foals are conceived. Such changes could further affect herd dynamics.
- 65. None of these risks were considered as part of the pesticide's initial registration.
- 66. On May 19, 2015, Friends of Animals submitted a Petition to EPA requesting that the Administrator conduct a Special Review, pursuant to 40 C.F.R. § 154.1 *et seq.*, to consider cancelling or altering the registration of ZonaStat-H in light of this new evidence.
- 67. The Petition also requested that the Administrator hold a hearing pursuant to 7 U.S.C. § 136(d)(b)(2).
- 68. On December 15, 2016, EPA made a final decision on Friends of Animals' Petition concluding that initiating a Special Review is not warranted at this time.
- 69. EPA did not consider new information about PZP as documented in Friends of Animals' Petition.
- 70. EPA did not consider the adverse impact of PZP on non-target animals or the environment.
 - 71. Instead, EPA deferred consideration of the adverse effects of PZP to BLM.
 - 72. EPA declined to hold a hearing.

CLAIM FOR RELIEF

FIRST CAUSE OF ACTION

- 73. Friends of Animals incorporates every allegation contained in the preceding paragraphs of this complaint.
- 74. EPA abused its discretion in improperly refusing to conduct a Special Review of ZonaStat-H to determine whether to initiate proceedings to cancel or reclassify the pesticide despite new scientific evidence.
- 75. A listed regulatory criteria to initiate Special Review is specifically intended to address the harmful effects of pesticides on nontarget organisms that are unintentionally exposed to a pesticide in the environment. 40 C.F.R. 154.7(a)(3).
- 76. The foals of wild horses exposed to PZP are nontarget organisms unintentionally exposed to PZP.
- 77. Scientific evidence shows that the exposure to PZP may otherwise pose a risk to the environment, including non-target wild horses, of sufficient magnitude to merit a determination whether the use of PZP offers offsetting benefits to justify continued registration.
- 78. EPA wrongfully determined that another agency, BLM, is responsible to decide whether ZonaStat-H meets the criteria for special review.
- 79. EPA's actions in refusing to conduct a special review for PZP or to hold a hearing to determine if registration of PZP should be canceled or reclassified, are arbitrary and capricious, an abuse of discretion, and not in accordance with law or required procedure in violation of the APA, 5 U.S.C. § 706.

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PRAYER FOR RELIEF

Friends of Animals respectfully requests that this Court enter judgment providing the following relief:

- A. Declare that Defendants acted arbitrarily and capriciously, abused their discretion, and otherwise acted in violation of the law or required procedures in denying the actions requested in the Petition, in refusing to initiate a Special Review, and/or in denying a public hearing to determine if the registration of PZP should be canceled or reclassified;
- B. Issue an order directing Defendants to reconsider Friends of Animals' Petition, to conduct a Special Review of PZP and/or to conduct proceedings to cancel or reclassify PZP;
- C. Issue an order requiring Defendants to suspend registration of PZP during the Special Review and/or proceedings to cancel or reclassify;
- D. Award Friends of Animals reasonable fees, expenses, costs and disbursements, including attorneys' fees associated with this litigation under the Equal Access to Justice Act, 28 U.S.C. § 2412; and
- E. Grant Friends of Animals such additional relief as the Court deems just and proper.

Dated: September 8, 2017. Respectfully Submitted,

/s/ R. Scott Jerger

R. Scott Jerger, Oregon Bar No. 023377

/<u>s/ Michael Harris</u> (pro hac vice motion pending)

Michael Ray Harris, DC Bar # C00049

Attorneys for Plaintiff Friends of Animals

Case 2:17-cv-01410-SU Document 1-1 Filed 09/08/17 Page 1 of 1 CIVIL COVER SHEET

JS 44 (Rev. 06/17)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the

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(c) Attorneys (Firm Name, Address, and Telephone Number) R. Scott Jerger, Field Jerger LLP, American Bank Building 621 SW Morrison Street, Suite 1225 Portland, OR 97205; Telephone (503) 228-9115				Attorneys (If Kn	nown)						
II. BASIS OF JURISDI	CTION (Place an "X" in Oi	ne Box Only)		TIZENSHIP O		INCIP	AL PARTIE				
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VI. CAUSE OF ACTIO	ON Federal Insecticion of ca	de, Fungicide, and	Rodent	icide Act, 7 U.S.	C. § 1	36n(a);	and Adminis				
VII. REQUESTED IN COMPLAINT:		hearing on Registered Pesticide ZonaStat-H (registration No. 86833-1) DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: □ Yes ▼No									
VIII. RELATED CASI	E(S) (See instructions):	JUDGE				DOC	KET NUMBER				
DATE SIGNATURE OF ATTORNEY OF RECORD 09/08/2017 FOR OFFICE USE ONLY											
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